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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/815,341	03/22/2001	Nancy J. Bump	BBC-069	4413	
75	590 11/21/2005		EXAM	INER	
Gayle B. O'Brien			SMITH, CAROLYN L		
Abbott Biorese	arch Center			D . DDD . DD . DDD	
100 Research D	Drive		ART UNIT	PAPER NUMBER	
Worcester, MA	A 01605-4314		1631		

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
Advisory Action	09/815,341	BUMP ET AL.					
Before the Filing of an Appeal Brief	Examiner	Art Unit					
	Carolyn L. Smith	1631	-				
The MAILING DATE of this communication appe	ears on the cover sheet with the c	correspondence add	ress				
THE REPLY FILED 24 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.							
. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of							
this application, applicant must timely file one of the folloplaces the application in condition for allowance; (2) a N (3) a Request for Continued Examination (RCE) in compfollowing time periods:	owing replies: (1) an amendment, a otice of Appeal (with appeal fee) in	ffidavit, or other evide compliance with 37 (	ence, which CFR 41.31; or				
a) The period for reply expires 4 months from the mailing date of the final rejection.							
b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no							
event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO							
MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f Extensions of time may be obtained under 37 CFR 1.136(a). The date on		) and the appropriate exte	oncion foo have				
been filed is the date for purposes of determining the period of extension a CFR 1.17(a) is calculated from: (1) the expiration date of the shortened st above, if checked. Any reply received by the Office later than three month earned patent term adjustment. See 37 CFR 1.704(b).	and the corresponding amount of the fee. atutory period for reply originally set in the	The appropriate extension final Office action; or (2)	on fee under 37 as set forth in (b)				
NOTICE OF APPEAL  2. M The Notice of Appeal was filed on 24 October 2005. A h	wiof in compliance with 27 CER 41	27 must be filed within	n two months of				
<ol> <li>The Notice of Appeal was filed on <u>24 October 2005</u>. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the</li> </ol>							
appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).							
AMENDMENTS							
3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because							
<ul> <li>(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);</li> <li>(b) ☐ They raise the issue of new matter (see NOTE below);</li> </ul>							
(c) $\square$ They are not deemed to place the application in be		educing or simplifying	the issues for				
appeal; and/or (d)☐ They present additional claims without canceling a corresponding number of finally rejected claims.							
NOTE: (See 37 CFR 1.116 and 41.33(a))		jootoa olamio.	•				
4. The amendments are not in compliance with 37 CFR 1.		ompliant Amendment	(PTOL-324).				
5. 🔲 Applicant's reply has overcome the following rejection(s	3):	·	,				
<ol> <li>Newly proposed or amended claim(s) would be a the non-allowable claim(s).</li> </ol>	allowable if submitted in a separate	, timely filed amendm	ent canceling				
7. 🛛 For purposes of appeal, the proposed amendment(s): a) 🗌 will not be entered, or b) 🖾 will be entered and an explanation of							
how the new or amended claims would be rejected is pro The status of the claim(s) is (or will be) as follows:	ovided below or appended.						
Claim(s) allowed:							
Claim(s) objected to:							
Claim(s) rejected: <u>21-27,32 and 33</u> . Claim(s) withdrawn from consideration: <u>1-20,28-31 and</u> :	34-88						
AFFIDAVIT OR OTHER EVIDENCE	<del>54 50</del> .						
3. The affidavit or other evidence filed after a final action, b because applicant failed to provide a showing of good ar and was not earlier presented. See 37 CFR 1.116(e).							
The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will <u>not</u> be entered because the affidavit or other evidence failed to overcome <u>all</u> rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).							
10. The affidavit or other evidence is entered. An explanation of the control	on of the status of the claims after e	entry is below or attac	ched.				
<ol> <li>The request for reconsideration has been considered by See Continuation Sheet.</li> </ol>	•		nce because:				
12.  Note the attached Information Disclosure Statement(s).	(PTO/SB/08 or PTO-1449) Paper	No(s)					
13.  Other:		•					

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' arguments have been considered but are unpersuasive for the reasons discussed below. Consequently, the 35 USC 112, 1st paragraph, rejections (lack of scope of enablement and lack of written description) and the 35 USC 103 (a) rejections are maintained.

#### 35 USC 112, 1st paragraph, lack of scope of enablement rejection

Applicants' summarize the rejection. Applicants' maintain previously set forth arguments. Examiner maintains already set forth response to those unpersuasive arguments. Applicants summarize the Drenth article which demonstrates the unpredictability in the trial and error procedures performed in the protein crystallization science. Applicants argue that Drenth states a standard procedure for crystallizing a protein. This statement is found unpersuasive as it is well known to be a science involving unpredictability which does not make it a routine procedure. Applicants state they have provided crystallization conditions in their specification to enable one skilled in the art to make crystals. Again, it is reiterated that Applicants have successfully provided enablement for atomic coordinates for residues 802-1124 of Tie-2 and Inhibitor complex, but does not provide enablement for the atomic coordinates of an unbound version of a Tie-2 polypeptide or atomic coordinates of the complete polypeptide of Tie-2 and Inhibitor complex. Due to the unpredictability in this art, only atomic coordinates specifically mentioned in the originally filed disclosure are enabled.

### 35 USC 112, 1st paragraph, lack of written description rejection

Applicants summarize the rejection. Applicants argue that the catalytic domain of Tie-2 (residues 802-1124) must be present in order for a compound to inhibit the Tie-2 protein, so that it doesn't matter whether the unbound or entire Tie-2 polypeptide and inhibitor complex is being used. This is an allegation without factual support. It is well known in the art that compounds change shape and configuration depending on their bound or unbound state. Applicants have demonstrated that they had possession at the time the invention was filed of the catalytic domain of Tie-2 according to the atomic coordinates specifically recited in the originally filed disclosure. Applicants mention the "comprising" terminology. Because this terminology encompasses other atomic coordinate possibilities, besides those specifically set forth in the specification, these other atomic coordinate possibilities lack adequate written description.

## 35 USC 103(a) rejection

Chen et al. in view of In re Gulack

Applicants argue that obtaining crystal coordinates is one of the steps in the instant invention. It is noted that instant claim 21 recites obtaining atomic coordinates. Applicants argue that the atomic coordinates of the crystal are functionally related to the method of claim 21 because the atomic coordinates identify the active subsites of Tie-2, which in turn allows one to identify or design an inhibitor of Tie-2. This statement is found unpersuasive as coordinates do not actively play a role which alters computer system functionality.

#### Chen et al. in view of In re Gulack and In re Best and In re Fitzgerald and Ziegler

Applicants note that their previous arguments regarding Ziegler's extracellular domain and Applicants' catalytic domain of Tie-2. It is reiterated that the instant claims do not state the compound must bind to the catalytic domain of Tie-2, instead the compound must bind to one or more active sites. Applicants refer to page 3, lines 21-25 of their specification. While claims are to be read in light of the specification, it is noted that limitations of the specification are not to be directly read into the claims unless those limitations are specifically set forth in the claims. Applicants are encouraged to read their claims carefully to understand that their claims do not specifically state the compound must bind to the catalytic domain.

# Chen et al. in view of Vikkula et al. and In re Best and In re Fitzgerald

Applicant argues similar arguments as above that the compound must bind to the catalytic domain. Careful reading of the claims would reveal that the compound does not have to bind to the catalytic domain of Tie-2, instead the compound must bind to one or more active sites. It is noted that an "active site" may be broadly construed to be any binding site on a protein, and it is not specifically defined by the instant specification to be a catalytic domain. Applicants' arguments are deemed unpersuasive.

MARJORIE A. MORAN PRIMARY EXAMINER Mocyair a. Moran 11/9/05